

U.S.S.N. 10/506,345  
Atty. Docket No. 1103326-0777  
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**REMARKS**

**I. Petition for Extension of Time**

Applicants herewith petition the Commissioner for Patents to extend the time for response to the Office action mailed April 10, 2006 for two (2) months from July 10, 2006 to September 10, 2006. Authorization is given to charge the extension of time fee of \$450.00 (37 C.F.R. §1.136 and §1.17) to Deposit Account No. 23-1703. Any deficiency or overpayment should be charged or credited to the above numbered deposit account.

**II. Amendments**

Claim 29, which was withdrawn from consideration, has been canceled. An abstract on a separate sheet is submitted herewith.

The disclosure appearing at page 4, lines 9-10 has been amended to clarify that it is the  $\text{NHR}_1\text{R}_2\text{R}_3^+$  salt of omeprazole or esomeprazole that is characterized by a pKa value.

Applicants submit that the amendment is supported by original claims 4-5. As discussed below, pKa is an inherent physiochemical characteristic of any drug compound. It is conventional practice to use the pKa value as a dissociation constant of a drug. In the present case, the drug compound is the  $\text{NHR}_1\text{R}_2\text{R}_3^+$  salt of omeprazole or esomeprazole. Therefore, the amendment at page 4, lines 9-10 clarifies the disclosure without adding any new matter. Furthermore, the amended specification comports with previously presented claims 4, 5, 21 and 22 which were deemed to be supported by the original disclosure.

**III. Claim Rejections – 35 U.S.C. §112**

Claims 1-5, 8, 10, 11, 15, 17-25, 27 and 28 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and claim the subject matter which Applicant regards as the invention.

Claims 4, 5, 10 and 21-24 are alleged to lack antecedent basis for the recited limitations. It appears that the Examiner may not have intended to include claim 23 which is directed to a specific compound embraced by the genus defined by claim 18. Dependent claims 4, 5, 21 and 22 recite that the pKa of the compound of independent claim 1 or 18, whichever the case may be,

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is equal to or greater than about 10 or 10.5. The Examiner states, however, that claims 1 and 18 fail to clearly claim what is intended by Applicant since the claims do not recite any pKa values.

The claimed invention is directed to a new drug compound, i.e., alkylammonium salts of omeprazole and esomeprazole. An inherent physiochemical characteristic of any drug compound is the pKa value. For almost all drugs, the dissociation constants are reported as pKa. Dissolution rate is the rate at which the drug solids dissolve in a dissolution media. Therefore, it is entirely appropriate that dependent claims 4, 5, 21 and 22 refer back to and further limit the drug compound of claim 1 or 18 by reciting a pKa value (37 C.F.R. §1.75(c)). At least to the person of ordinary skill in the art, there is nothing indefinite about the meaning of claims 4, 5, 21 or 22.

Similarly, dependent claims 10 and 24 refer back to and further limit the drug compound of claim 1 or 18 by specifying the crystalline form of the compound (See Figures 1 and 2). This is proper in view of 37 C.F.R. §1.75(c) and unambiguous to the person of ordinary skill in the art.

Applicant have made a good faith attempt to respond to the rejection of claims 4, 5, 10, 21, 22 and 24 for lack of antecedent basis. If the preceding comments are not responsive, Applicant respectfully requests the Examiner to more clearly articulate the basis for the rejection in the next Action.

Claims 1-5, 8, 10, 11, 15, 17-25, 27 and 28 are alleged to contain the tradename omeprazole or esomeprozaole. Applicant respectfully submits that the basis for the rejection is incorrect. The tradenames are actually Prilosec® (omeprazole) and Nexium® (esomeprazole magnesium). Omeprazole and esomeproazole are the generic names for the trademark protected name Prilosec® and Nexium, respectively. In support, Applicant submits herewith a copy of a relevant page from The Merck Index (13th Ed.). The recitation of the generic names in the claims is proper and indefinite.

For all of the foregoing reasons, withdrawal of the §112 rejection is requested.

FROM W&C LLP 19TH FL.

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**IV. Conclusion**

In view of the claim amendments and remarks herein, the application is in condition for allowance.

Authorization is hereby given to charge any fee due in connection with this communication to Deposit Account No. 23-1703.

Dated: 28 August 2006

Respectfully submitted,

  
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Enclosure: The Merck Index (13th Ed.) – one sheet